

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

AMGEN INC. and	)	
KAI PHARMACEUTICALS, INC.,	)	
	)	
Plaintiffs,	)	C.A. No. 21-662 (MN)
	)	(Consolidated)
v.	)	
	)	<b>REDACTED - PUBLIC VERSION</b>
AUROBINDO PHARMA LIMITED, et al.,	)	
	)	<b>Original Version Filed: November 29, 2022</b>
Defendants.	)	<b>Redacted Version Filed: December 1, 2022</b>

**STIPULATION AND ORDER**

Plaintiffs Amgen Inc. and KAI Pharmaceuticals, Inc. (“Plaintiffs”), and Defendants Aurobindo Pharma Limited, Aurobindo Pharma USA Inc., Eugia Pharma Specialties Limited, and Auromedics Pharma LLC, (collectively, “Aurobindo”), stipulate and agree as follows:

1. Aurobindo has filed Abbreviated New Drug Application (“ANDA”) No. 215840 with the United States Food and Drug Administration seeking approval for Aurobindo’s generic version of Parsabiv® (etelcalcetide) injection for intravenous use at strengths of 2.5 mg/0.5 mL, 5 mg/mL, and 10 mg/2 mL (“Aurobindo’s Proposed ANDA Product”).

2. Plaintiffs have sued Aurobindo for patent infringement, asserting that the submission of Aurobindo’s ANDA No. 215840 constitutes an act of infringement of U.S. Patent Nos. 9,820,938 (the “’938 patent”); 10,344,765 (the “’765 patent”); and 11,162,500 (the “’500 patent”). Aurobindo has asserted various defenses and counterclaims in response to Plaintiffs’ Complaint.

3. The parties wish to narrow the issues in dispute and have reached agreement on the infringement issues set forth below.

4. Specifically, the parties stipulate and agree that Aurobindo’s submission of ANDA No. 215840 infringed, and the making, using, offering to sell, selling, or importing Aurobindo’s

Proposed ANDA Product will infringe or induce infringement of the following claims of the following patents, so long as each respective claim is not found invalid or unenforceable:

- a. Claims [REDACTED], and [REDACTED] of the '938 patent;
- b. Claims [REDACTED], and [REDACTED] of the '765 patent; and
- c. Claims [REDACTED], and [REDACTED] of the '500 patent.

5. Plaintiffs are not asserting any other claims of the '938, '765, or '500 patents against Aurobindo in this action based on the filing of Aurobindo's Proposed ANDA Product or based on the making, using, offering to sell, selling, or importing of Aurobindo's Proposed ANDA Product as currently described in Aurobindo's ANDA No. 215840.

6. Plaintiffs hereby agree not to further pursue fact discovery from Aurobindo in this case with respect to the above-listed patents regarding the manufacturing or preparation of the etelcalcetide hydrochloride active pharmaceutical ingredient used in making Aurobindo's Proposed ANDA Product; DMF No. 035386 for etelcalcetide hydrochloride; samples of the etelcalcetide hydrochloride API used in Aurobindo's Proposed ANDA Product; samples of any finished dosage form of Aurobindo's Proposed ANDA Product; the formulation of Aurobindo's ANDA Product, including fact discovery regarding the manufacturing of, excipients used in, quantity of any excipient in, or function of any excipient in Aurobindo's Proposed ANDA Product. The parties agree that Amgen may still take discovery regarding Aurobindo's development of its Proposed ANDA Product.

7. Plaintiffs hereby agree to withdraw their present notices of deposition to Mr. Adarsh Jain (Dkt. 97) and Mr. V. Naga Prasad (Dkt. 98). Plaintiffs have also noticed the deposition of Aurobindo pursuant to Rule 30(b)(6) (Dkt. 105). Upon completion of that deposition of

Aurobindo, should Plaintiffs believe they need an additional deposition of an Aurobindo fact witness in his or her individual capacity, the parties shall meet and confer regarding the identity of such witness and negotiate in good faith to make such witness available for deposition. The parties agree that, if the deposition of the additional Aurobindo fact witness proceeds, it may take place outside of the time period set for fact discovery in the Court's Scheduling Order (Dkt. 115). Unless following the parties' good faith negotiations, one of the individuals listed in Aurobindo's Initial Disclosures Pursuant to Rule 26(a)(1) is identified and deposed in their individual capacity, Aurobindo agrees that it will not call any of those individuals to testify at trial.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

*/s/ Cameron P. Clark*

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November 29, 2022

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 Limited, Aurobindo Pharma USA Inc., Eugia  
 Pharma Specialties Limited and Auromedics  
 Pharma LLC*

SO ORDERED this \_\_\_\_ day of \_\_\_\_\_, 2022.

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UNITED STATES DISTRICT JUDGE